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Early experience of transcatheter aortic valve implantation (TAVI) procedure in Isfahan, Iran

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Abstract

BACKGROUND: Valve replacement is an optional treatment for patients with severe aortic stenosis (AS) and is associated with a better prognosis and improved quality of life. However, surgical valve replacement may result in severe complications, especially in the elderly. Transcatheter aortic valve replacement (TAVR) for treating symptomatic aortic stenosis has expanded exponentially, becoming a therapeutic option for intermediate- and high-risk patients. To thoroughly examine and monitor its practices and improve outcomes, our TAVI center in Isfahan established a detailed registry as the primary center for the TAVI procedure.

METHODS: This prospective study was conducted among all patients who underwent the TAVR procedure from September 2022 to December 2023 in Isfahan. Baseline characteristics (demographic, clinical, and procedural), 30-day outcomes, and one-year mortality data were collected.

RESULTS: A total of 50 patients underwent the TAVI procedure in Isfahan during our registry. Of these, 56% were male, and the mean age was 77.8 ± 6.7 years. The mean calculated STS score was 5.6. Cardiac death occurred in 4 patients (8%), one (2%) experienced a major vascular complication, 5 (10%) required new pacemaker implantation, and acute kidney injury was observed in 14%. Fever/sepsis occurred in 16%, cardiac tamponade in 6%, one patient (2%) had moderate AI, two patients experienced coronary obstructions, and one suffered a major cerebrovascular accident. Additionally, 4 patients (8%) developed atrial fibrillation, 1 (2%) had ventricular tachycardia, and 6 (12%) experienced AV block.

CONCLUSION: We have shown good both 30-days outcome and one year mortality in our registry that could be a proper option in treating severe AS with comorbidities instead of surgical aortic valve replacement.

Keywords: Transcatheter Aortic; Valve Replacement; Registry; Outcomes; Mortality

Introduction

Aortic stenosis is a prevalent valve disorder in clinical practice and a common reason for valve surgery, affecting 2–7% of individuals over 65 years old. Severe symptomatic aortic stenosis has a poor prognosis with conservative treatment[1]. Valve replacement is the preferred treatment, offering a better prognosis and improved quality of life[2]. However, surgical valve replacement can lead to severe complications, particularly in elderly patients with significant comorbidities, resulting in 30% of these patients not undergoing surgery[3].

Transcatheter aortic valve replacement (TAVR) has rapidly become a therapeutic option for intermediate- and high-risk patients with symptomatic aortic stenosis[4-7]. Despite its benefits, TAVR can pose challenges, such as the risk of cerebrovascular accidents (CVA)[8]. Since real-life outcomes may differ from those in randomized trials, it is crucial for each TAVI center to thoroughly examine and monitor its practices to improve outcomes. Maintaining a detailed registry of TAVI patients is essential for identifying those at risk for major cardiac events (MACE)[9]. As one of the largest TAVI centers in Iran, we decided to register all patients undergoing TAVI in Isfahan to identify and address complications and improve results.

Methods

A prospective study was conducted on all patients who underwent the TAVR procedure in Isfahan from September 2022 to December 2023. Baseline characteristics including demographic, clinical, and procedural data as well as 30-day outcomes and one-year mortality data were collected. Pre-procedural data encompassed body mass index (BMI), medical history with comorbidities, hematological lab results, cardiac computed tomography (CT) scans, echocardiographic measurements, and calculated STS (Society of Thoracic Surgeons) scores. Procedural data included details on access site puncture, valve type and size, vascular closure methods, and cardiac pacing.

The 30-day follow-up focused on defined MACE, mortality (cardiac and all-cause mortality), new pacemaker implantation, aortic regurgitation (AR), aortic rupture, massive pericardial effusion and cardiac tamponade, valve embolization, valve thrombosis, sepsis, hematological disturbances (anemia and thrombocytopenia), and contrast-induced nephropathy (CIN).

MACE was defined as death, major stroke, and vascular complications (VC). In addition to post-procedural data, the number of hospitalization days following the procedure was recorded. Major bleeding was defined as a hemoglobin decrease of more than 2 g/dL. Major CVA was diagnosed if significant disability or death occurred post-procedure. Thrombocytopenia was considered present if there was a decrease of more than 50% in platelet count. Contrast-induced nephropathy (CIN) was defined as a 25% increase in serum creatinine (Cr) from baseline or a 0.5 mg/dL increase in absolute Cr value within 48–72 hours post-TAVI[10].

Procedural details

Transfemoral TAVI procedures were primarily performed under local anesthesia. For peri-TAVI anticoagulation, unfractionated heparin was administered as a bolus of 50–70 IU/kg of body weight. Suture-mediated vascular closure devices (ProGlide) were used for access site hemostasis. Post-TAVI, patients were prescribed clopidogrel (75 mg daily for three months) and aspirin (80 mg daily for life). Two types of valves were used: balloon-expandable valves (Sapien 3 or MyVAL) versus self-expandable valves (Portico). With fluoroscopic guidance, arterial (one or two) and venous access points were achieved. A temporary pacing wire was positioned in the right ventricle (RV) via the femoral vein and used for rapid ventricular pacing (180–220 bpm) during balloon inflation and valve deployment.

After crossing the aortic valve with a soft-tipped wire using an Amplatz Left or Judkins Right 4 catheter, the wire is exchanged for a stiff

wire with a curved tip, and then the device is delivered to the LV. In some cases of significant tortuosity, a crossover technique (placing a wire in the contralateral artery) was used to facilitate valve or balloon delivery. After verifying the valve position with an aortogram, balloon-expandable valves were deployed using balloon inflation up to nominal pressure. If there was more than mild AR, post-dilation was performed. A final check with an aortogram and echocardiography was then conducted.

The 23- and 25-mm Portico valves are compatible with an 18-F delivery system, whereas the 27- and 29-mm valves require a 19-F delivery system. These valves can be inserted via transfemoral access and, when used with the Solo-Path re-collapsible introducer (St. Jude Medical, Inc.), feature a minimal 13.5-F insertion profile. Temporary pacemaker (TPM) support is maintained for at least 24 hours post-TAVI procedure and is removed if no conduction defects are observed.

Sampling Method and Sample Size Estimation

Considering that TAVI is not a prevalent procedure, the number of patients who underwent it is limited. A total of 50 patients underwent TAVI between September 2022 and December 2023 in Isfahan; therefore, all were included in our study. No sampling method was used. All patients with severe AS and a high STS score who were at high risk for surgery and underwent TAVI were included in the study.

Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD), while categorical variables are presented as number (percent). The Shapiro-Wilk test was used to assess the normality of continuous variables. To evaluate differences between groups, we used the independent samples t-test for continuous variables when the statistical assumptions of normality and homogeneity of variance were met. The normality assumption was checked using the Kolmogorov-Smirnov test, while the homogeneity of variance assumption was verified using Levene's test. For continuous variables with non-normal distributions, the Mann-Whitney U test was applied.

We also used the Chi-Squared test for categorical variables. The Fisher exact test was applied when the assumptions of the Chi-Squared test were not met. A p-value of <0.05 was considered statistically significant. Data analysis was performed using the Statistical Package for the Social Sciences (SPSS 26).

Results

Fifty patients who underwent the TAVI procedure in Isfahan between September 2022 and December 2023 were included in our study. The mean age of the patients was 77.8 ± 6.7 years, with the oldest being 89 years old and the youngest 54 years old. Fifty-six percent of them were male. The mean calculated STS score was 5.6 ± 4.4, with a maximum of 23%. The mean BMI was 25.5 ± 3.7.

Eleven patients (22%) had chronic respiratory disease, defined as chronic obstructive pulmonary disease (COPD) or obstructive sleep apnea (OSA), requiring home oxygen therapy. Seventeen patients (34%) had chronic kidney disease (GFR <60), 22 (44%) had diabetes, 37 (74%) had hypertension (HTN), and 17 (34%) had heart failure (LVEF <40%) (Table 1).

The mean left ventricular (LV) ejection fraction (EF) was 46.2 ± 10.9, and the mean trans-aortic gradient was 53.8 ± 16.5 mmHg. The mean aortic annulus, calculated using cardiac CT, was 23.4 ± 3.2 mm and was significantly smaller among females (21.7 ± 2.5 mm). The mean calcium score was 3,191.6 ± 1,392.7. The mean left main (LM) and right coronary artery (RCA) ostial heights were 12.1 ± 3.1 mm and 14.0 ± 3.4 mm, respectively, both of which were significantly lower in females.

Imaging and hematological lab data is shown in Table 2 Average days of hospitalization after TAVI was 4.7 of days. Thirty-six (72%) patients had tricuspid aortic valve and 14 (28%) patients had bicuspid aortic valve included either

Table 1. Baseline characteristics of patients under transcatheter aortic valve implantation procedure

Variables	Total (N=50)	Male (N=28)	Female (N=22)	P-value
Age (years)	77.8 ± 6.7	78.6 ± 8.0	76.9 ± 4.6	0.100[a]
BMI (kg/m²)	25.5 ± 3.7	25.0 ± 3.7	26.0 ± 3.7	0.389[a]
Respiratory disorders (yes)*	11 (22.0)	6 (21.4)	5 (22.7)	1.00[b]
HF (yes)	17 (34.0)	11 (39.3)	6 (27.3)	0.373[c]
CKD (yes)	17 (34.0)	15 (53.6)	2 (9.1)	0.001c
Diabetes (yes)	22 (44.0)	11 (39.3)	11 (50.0)	0.449[c]
Hypertension (yes)	37 (74.0)	18 (64.3)	19 (86.4)	0.077[c]
STS score	5.6 ± 4.4	6.0 ± 5.5	5.1 ± 2.5	0.667[a]
Hospitalization duration (days)	4.7 ± 3.5	4.6 ± 3.9	4.7 ± 2.8	0.491[a]

Data are presented as mean ± SD or number (%).
P< 0.05 was considered statistically significant. BMI: Body Mass Index, HF: Heart Failure, CKD: Chronic kidney disease, STS: Society of Thoracic Surgeon
*Chronic Obstructive Pulmonary Disease or obstructive sleep apnea with O_2 dependency.
[a] Calculated by the Mann-Whitney U test.
[b] Calculated by the Fisher's Exact test.
[c] Calculated by the Chi-Square test.

Table 2. Baseline imaging and lab data in patients under transcatheter aortic valve implantation procedure

Variables	Total (N=50)	Male (N=28)	Female (N=22)	P-value
LVEF (%)	46.2 ± 10.9	45.0 ± 12.5	47.6 ± 8.3	0.764[a]
Mean aortic valve gradient (mmHg)	53.8 ± 16.5	52.4 ± 16.4	55.5 ± 16.9	0.525[a]
AV annulus diameter (mm)	23.4 ± 3.2	24.7 ± 3.0	21.7 ± 2.5	< 0.001[a]
BICUSPID valve	14 (28.0)	9 (32.1)	5 (22.7)	0.462[b]
TRICUSPID valve	36 (72.0)	19 (67.9)	17 (77.3)	
Calcium score	3191.6 ± 1392.7	3457.7 ± 1439.5	2864.9 ± 1290.3	0.140[b]
LM ostial height (mm)	12.1 ± 3.1	12.2 ± 3.2	11.9 ± 3.2	0.052[a]
RCA ostial height (mm)	14.0 ± 3.4	15.0 ± 3.0	12.6 ± 3.6	0.001[a]
Hemoglobin (g/dl)	12.8 ± 1.9	13.0 ± 1.9	12.4 ± 1.9	0.286[b]
Creatinine (mg/dl)	1.3 ± 0.4	1.4 ± 0.4	1.0 ± 0.2	< 0.001[a]
WBC	8552.0 ± 3312.5	8446.4 ± 3754.9	8686.4 ± 2727.9	0.577[a]

Data are presented as mean ± SD or number (%).
P< 0.05 was considered statistically significant. LVEF: Left Ventricular Ejection Fraction, AV: Aortic Valve, LM: Left Main, RCA: Right Coronary Artery, WBC: White Blood cell
[a] M [a] Calculated by the Mann-Whitney U test
[b] Calculated by an Independent sample t-test

anatomical or functionally bicuspid. There was no significant difference between gender and number of aortic cusps. In 41 (82%) cases, balloon expandable valves include MY-VAL or SAPIEN 3 were used, and in rest of patients (18%), self-expandable valve (PORTICO) was used (Table 3). All procedures were done under conscious sedation, rapid RV pacing was performed during balloon inflation and valve deployment, all patients received prophylactic antibiotics included Cephalothin and vancomycin. Vascular access closure devise named Proglide was used in all patients while it was failed in one patient that was repaired by surgery.

We had 4 (8%) deaths among all patients, none of which occurred during or immediately after the procedure. One patient developed loss of consciousness the day after the TAVI procedure due to a major CVA. They were intubated and remained in the ICU for two weeks before passing away, despite the valve functioning properly in serial echocardiography. Another patient experienced refractory pulmonary edema after the procedure, which was attributed to severe mitral regurgitation that worsened following TAVI. She underwent surgical MVR based on the heart team's recommendation but passed away during the operation. One death resulted from severe sepsis, which led to multi-organ failure. The final death occurred in a patient who developed cardiac tamponade post-procedure. Although the tamponade was successfully drained via closed pericardiocentesis, the patient succumbed to sudden cardiac arrest 48 hours later.

One (2%) major vascular complication occurred—perforation of the right external iliac artery, which was successfully treated with a covered stent. Additionally, three minor vascular complications were observed. One patient developed an arteriovenous fistula requiring surgical repair, while two cases of major hematoma were managed with external compression. One Proglide failure was noted and subsequently treated surgically.

Five (10%) patients required new pacemaker implantation. Thrombocytopenia, defined as either a greater than 50% drop in platelet count from baseline or a count below 60,000, was observed in 10 (20%) patients. Significant bleeding was reported in 14 (28%) patients. Other peri-procedural complications included AKI (14%), fever (12%)/sepsis (4%), cardiac tamponade (6%), and moderate AI in one (2%) patient.

During the procedure, two cases of coronary obstruction occurred, both of which were immediately treated with stent placement. Two patients experienced cerebrovascular accidents (CVA) one major case led to death, while the other was minor and gradually resolved. Arrhythmias occurring during and after the procedure included AF in 4 (8%) patients, VF in 1 (2%) patient, and AV block in 6 (12%) patients (Table 4).

Since TAVR in bicuspid aortic valves is more complex and may influence early and late outcomes, we investigated peri-procedural

Table 3. Procedural and valve characteristic in patients underwent trans catheter aortic valve implantation procedure

Variables		Total (N=50)	Male (N=28)	Female (N=22)	P-value
Valve type	SAPIEN (yes)	29 (58.0)	15 (53.6)	14 (63.6)	0.363[a]
	PORTICO (yes)	9 (18.0)	4 (14.3)	5 (22.7)	
	MYV AL (yes)	12 (24.0)	9 (32.1)	3 (13.6)	
Valve size (mm)		25.0 ± 2.2	25.9 ± 2.1	23.9 ± 1.8	0.001[b]

Data are presented as mean ± SD or number (%).
P< 0.05 was considered statistically significant.
[a] Fisher Exact Test Calculated by the Fisher's Exact test.
[b] Mann-Whitney U Calculated by the Mann-Whitney U test.

and 30-day outcomes in bicuspid aortic valves (functional or anatomical) compared to tricuspid valves. Results indicated a higher rate of new PPM implantation in patients with bicuspid aortic valves. Cardiac tamponade was more frequent in patients with bicuspid valves, though it was associated with right ventricular perforation from the pacing lead. Results are shown in Table 5.

Discussion

Calcified AS is the most common reason of severe AS that leads to AVR in old aged patients; because of comorbidities in this group of patients, TAVR is the best option for treating AS. Selecting patients for TAVR should be performed in heart team. Our mortality rate was similar to other studies; 8% Comparing to 7.1 % in U.K TAVI registry[11], 7.5% in hospital mortality rate in a multi-center

Table 4. Periprocedural and 30-days outcomes in patients under transcatheter aortic valve implantation procedure

Variable		Total (N=50)	Male (N=28)	Female (N=22)	P-value
PPM implementation (yes)		5 (10.0)	3 (10.7)	2 (9.1)	1.000[a]
Major vascular complications (yes)		1 (2.0)	0 0.0)	1 (4.5)	0.440[a]
Minor vascular complication (yes)		3 (6.0)	2(7.0)	1 (4.5)	0.621[a]
Thrombocytopenia (yes)		10 (20.0)	5 (17.9)	5 (22.7)	0.732[a]
Major bleeding (yes)		14 (28.0)	7 (25.0)	7 (31.8)	0.594[b]
Fever / sepsis (yes)		8 (16.0)	6 (21.4)	2 (9.1)	0.278[a]
AKI (yes)		7 (14.0)	6 (21.4)	1 (4.5)	0.117[a]
Major CVA (yes)		1 (2.0)	1 (3.6)	0 (0.0)	1.000[a]
Minor CVA (Yes)		1 (2.0)	1 (3.6)	0 (0.0)	1.000[a]
AI (yes)		1 (2.0)	0 (0.0)	1 (4.5)	0.254[a]
Tamponade (yes)		3 (6.0)	1 (3.6)	2 (9.1)	0.415[a]
In hospital death (yes)		4 (8.0)	3 (10.7)	1 (4.5)	0.621[a]
Non-cardiac death (yes)		2(4.0)	2(7.0)	2(9.1)	
Peri-procedural death		0	0	0	
Coronary obstruction (yes)		2 (4.0)	1 (3.6)	1 (4.5)	1.000[a]
Arrhythmia	**None**	39 (78.0)	22 (78.6)	17 (77.3)	1.000[a]
	AF	4 (8.0)	2 (7.1)	2 (9.1)	
	VF	1 (2.0)	1 (3.6)	0 (0.0)	
	AV block	6 (12.0)	3 (10.7)	3 (13.6)	

Data are presented as mean ± SD or number (%).
P< 0.05 was considered statistically significant.
PPM permanent Pace Maker, CVA: Cerebrovascular Accident, AI: Aortic Insufficiency AF: Atrial Fibrillation, VF: Ventricular Fibrillation, AV: Atrioventricular
[a] Fisher-Exact Test Calculated by the Fisher's Exact test.
[b] Chi-square Calculated by the Chi-Square test.

Table 5. Periprocedural and 30-days outcomes in patients under transcatheter aortic valve implantation procedure by type of valve and CUSPS

Variable		Valve type			CUSPS type		
		SAPIEN / MYVAL N = 41	PORTICO N = 9	P-value	BICUSPID N=14	TRICUSPID N=36	P-value
PPM implementation (yes)		4 (9.8)	1 (11.1)	1.00[a]	4 (28.6)	1 (2.8)	0.018[a]
Major vascular complications (yes)		0 (0.0)	1 (11.1)	0.180[a]	0 (0.0)	1 (2.8)	1.00[a]
Minor vascular complication (yes)		4 (9.8)	0 (0.0)	0.583[a]	1 (7.1)	3 (8.3)	1.00[a]
Thrombocytopenia (yes)		7 (17.1)	3 (33.3)	0.358[a]	7 (50.0)	3 (8.3)	0.003[a]
Major bleeding (yes)		10 (24.4)	4 (44.4)	0.414[a]	4 (28.6)	10 (27.8)	1.00[a]
Fever / sepsis (yes)		4 (9.8)	4 (44.4)	0.026[a]	4 (28.6)	4 (11.1)	0.197[a]
AKI (yes)		5 (12.2)	2 (22.2)	0.595[a]	4 (28.6)	3 (8.3)	0.085[a]
Major CVA (yes)		1 (2.4)	0 (0.0)	1.00[a]	0 (0.0)	1 (2.8)	1.00[a]
Minor CVA (Yes)		0 (0.0)	1 (11.1)	0.180[a]	0 (0.0)	1 (2.8)	1.00[a]
AI (yes)		0 (0.0)	1 (11.1)	0.180[a]	0 (0.0)	1 (2.8)	1.00[a]
Tamponade (yes)		3 (7.3)	0 (0.0)	0.623[a]	3 (21.4)	0 (0.0)	0.019[a]
In hospital death (yes)		2 (4.9)	2 (22.2)	0.144[a]	3 (21.4)	1 (2.8)	0.061
Coronary obstruction (yes)		2 (4.9)	0 (0.0)	1.00[a]	1 (7.1)	1 (2.8)	1.00[a]
Arrythmia	**None**	4 (9.8)	0 (0.0)	0.529[a]	0 (0.0)	4 (11.1)	0.353[a]
	AF	1 (2.4)	0 (0.0)		0 (0.0)	1 (2.8)	
	VF	4 (9.8)	2 (22.2)		3 (21.4)	3 (8.3)	
	AV block	32 (78.0)	7 (77.8)		11 (78.6)	28 (77.8)	

Data are presented as mean ± SD or number (%).
P< 0.05 was considered statistically significant.
PPM: Permanent Pace Maker, AKI:Acute Kidney Disease, CVA: Cerebrovascular accident, AI: Aortic insufficiency , AF: Atrial Fibrillation, VF: Ventricular Fibrillation, AV: Atrioventricular
[a]Fisher exact Test Calculated by the Fisher's Exact test.

registry[12]. Our mortality could be impacted by small volume of our study and should be considered all of death occurred in first year of registry which experience was less than next year.

Like other TAVI registries, we used predictive models, specifically the STS score, to estimate the risk of mortality, which ranged from 1.4% to 23.8%, with a mean of 5.6%. This indicates that we were dealing with complex patients. However, there was no significant relationship between STS score values and procedural complications.

Our study utilized both balloon-expandable and self-expandable valves, with no significant differences observed in complications or 30-day outcomes. However, balloon-expandable valves were associated with a lower incidence

of new pacemaker implantation, reduced aortic insufficiency (AI), lower contrast volume usage, and shorter hospital stays[10].

According to the VARC-2 study, device success was lower in self-expandable valves, while the rate of new pacemaker implantation was higher in this group[11]. A multicenter TAVI registry reported that 39.3% of patients required permanent pacemakers, primarily due to permanent or intermittent third-degree atrioventricular (AV) block. The pacemaker implantation rate was 42.5% in the Medtronic CoreValve group (self-expandable) compared to 22.0% in the Sapien-Edwards group (balloon-expandable)[12].

Another study highlighted differences in pacemaker rates between the two TAVI systems. In a series by Eltchaninoff et al., the pacemaker implantation rate was 27.2% for the Medtronic CoreValve compared to 5.3% for the Sapien Edwards group[13]. Stroke, a known complication of TAVR, occurs less frequently than in surgical procedures[14].

Our study reported the lowest rate of major CVA at 2%, comparable to the rates observed in the PARTNER trial for intermediate-risk patients[15], as well as 2.8% by Ralf Zahn et al.[12] and 0.6% & 3.6% by Piezza et al.[16] and Eltchaninoff et al.[13], respectively.

Anemia is a known predictor of higher mortality and should be identified and corrected[17]. In our study, 14 patients (28%) experienced a drop in hemoglobin concentration of more than 2 g/dL, necessitating blood transfusion. Thrombocytopenia occurred in 10 (20%) patients, leading to a bleeding tendency, such as hematuria, which resolved spontaneously.

The rate of new pacemaker implantation was 10%, which was not significantly higher than other reported rates. There was no significant relationship between the type of valve and the rate of PPM implantation; however, it is recommended to avoid self-expandable valves in patients with pre-existing atrioventricular (AV) block or bundle branch block (BBB).

Vascular complications (VC) are another concern during the procedure and should be carefully managed. While most VCs are minor and do not adversely impact outcomes, evidence remains conflicting. Major VCs can influence 30-day and 1-year outcomes of TAVR, as demonstrated in the VARC-II trial[18].

We had one major VC, a perforation in the left external iliac artery, which was treated with a covered stent. Three minor VCs (6%) occurred: one arteriovenous (A-V) fistula and one access closure failure, both of which were repaired surgically, and one massive hematoma that was externally compressed. Studies have shown that underweight patients may experience more VCs than those with normal weight[18]. In our study, all four VCs occurred in patients with a BMI ranging between 25 and 29.

The final results of a study comparing Prostar-XL and the Perclose ProGlide showed a higher incidence of major VC and major bleeding with Prostar-XL[19]. We used ProGlide for all patients, while the operator checked the anatomical puncture site with fluoroscopic guidance before puncture. As noted above, we demonstrated the lowest incidence of vascular complications.

Pre-existing chronic kidney disease (CKD) is a common comorbidity among TAVI patients and negatively impacts both short- and long-term outcomes[20].

In our study, we found that seven patients (14%) developed acute kidney injury (AKI) after TAVI. With the exception of one case that resulted in death, all other patients were managed medically and did not require hemodialysis. Despite higher rates of AKI and CIN in our registry and other TAVI registries, TAVI patients still have better renal outcomes compared to those undergoing surgical AVR[21].

In our study, cardiac tamponade occurred in 6% of patients and was managed with closed pericardiocentesis. This rate is comparable with reports by Arie Pieter Kappetein et al. (0.9%)[11], Ralf Zahn et al. (1.8%)[12], Piazza et al. (1.4%)[16], and Eltchaninoff et al. (2%)[13], all of whom managed cardiac tamponade with closed

pericardiocentesis.

The prevalence of pre-existing AF varies widely across studies, ranging from 16% to 51.1%, with AF and AS sharing several risk factors[22]. Recent studies have shown increased mortality associated with both recent and remote AF[23]. We had two cases of coronary obstruction, which were predicted before the procedure due to low postural height. After obstruction occurred, we immediately stented the affected vessel.

According to the Society of Thoracic Surgeons' predicted risk of mortality (STS-PROM) calculator, female sex is a risk factor for mortality following surgical aortic valve replacement (SAVR). The Italian Observational Multicenter Registry (OBSERVANT) found that while female sex was linked to higher procedural mortality for SAVR, this was not the case for TAVR[24]. Our analysis showed no significant difference in outcomes between genders; however, further studies with a larger sample size are needed.

Our patients were discharged after an average of 4.7 ± 3.5 days, whereas the average hospitalization duration in the Cyprus registry was 3.6 ± 2.3 days, which is shorter than the duration following SAVR.

While TAVR in bicuspid aortic valves is more complex and may impact early or late outcomes, we investigated peri-procedural and 30-day outcomes in bicuspid aortic valves (functional or anatomical) compared to tricuspid valves. Our findings showed a higher rate of new PPM implantation in bicuspid aortic valves. Cardiac tamponade was more frequent in bicuspid valves; however, it was related to right ventricular (RV) perforation with pacing lead placement. The results are shown in Table 5.

Conclusion

We have shown good 30-days outcomes in our first TAVI registry; including low incidence of MACE, stroke, PPM implantation, and vascular complications. Rate of PPM implantation was higher among bicuspid valves.

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Conflict of interests

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Author's Contributions

Study Conception or Design: AKF
Data Acquisition: AM
Data Analysis or Interpretation: AM
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References

1. Aronow WS, Ahn C, Kronzon I, Nanna M. Prognosis of congestive heart failure in patients aged > or = 62 years with unoperated severe valvular aortic stenosis. Am J Cardiol. 1993 Oct 1;72(11):846-8. https://doi.org/10.1016/0002-9149(93)91081-r
2. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J. 2007 Jan;28(2):230-68. https://doi.org/10.1093/eurheartj/ehl428
3. Iung B, Cachier A, Baron G, Messika-Zeitoun D, Delahaye F, Tornos P, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J. 2005 Dec;26(24):2714-20. https://doi.org/10.1093/eurheartj/ehi471
4. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease. Polish Heart Journal (Kardiologia Polska). 2018;76(1):1-62. https://doi.org/10.1093/eurheartj/ehx391
5. Makkar RR, Thourani VH, Mack MJ, Kodali SK, Kapadia S, Webb JG, et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. 2020 Jan 29;382(9):799-809. https://doi.org/10.1056/nejmoa1910555
6. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011 Jun 9;364(23):2187-98. https://doi.org/10.1056/nejmoa1103510

7. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010 Oct 21;363(17):1597-607. https://doi.org/10.1056/nejmoa1008232
8. Writing Group Members; Mozaffarian D, Benjamin EJ, Go AS, Arnett DK, Blaha MJ, et al. Heart Disease and Stroke Statistics-2016 Update: A Report From the American Heart Association. Circulation. 2016 Jan 26;133(4):e38-360. https://doi.org/10.1161/cir.0000000000000350
9. Eftychiou C, Eteocleous N, Zittis I, Simamonian K, Ioannou A, Loukaidou P, et al. Outcomes of transfemoral transcatheter aortic valve implantation (TAVI) and predictors of thirty-day major adverse cardiovascular events (MACE) and one-year mortality. Hellenic J Cardiol. 2021 Jan-Feb;62(1):57-64. https://doi.org/10.1016/j.hjc.2020.09.011
10. Kellum JA, Lameire N, Aspelin P, Barsoum RS, Burdmann EA, Goldstein SL, et al. Work group membership. Kidney Int. 2012;2(1):10.1038.
11. Kappetein AP, Head SJ, Généreux P, Piazza N, Van Mieghem NM, Blackstone EH, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol. 2012 Oct 9;60(15):1438-54. https://doi.org/10.1016/j.jacc.2012.09.001
12. Zahn R, Gerckens U, Grube E, Linke A, Sievert H, Eggebrecht H, et al. Transcatheter aortic valve implantation: first results from a multi-centre real-world registry. Eur Heart J. 2011 Jan;32(2):198-204. https://doi.org/10.1093/eurheartj/ehq339
13. Eltchaninoff H, Prat A, Gilard M, Leguerrier A, Blanchard D, Fournial G, et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J. 2011 Jan;32(2):191-7. https://doi.org/10.1093/eurheartj/ehq261
14. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019 May 2;380(18):1695-705. https://doi.org/10.1056/nejmoa1814052
15. Thourani VH, Kodali S, Makkar RR, Herrmann HC, Williams M, Babaliaros V, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet. 2016 May 28;387(10034):2218-25. https://doi.org/10.1016/s0140-6736(16)30073-3
16. Piazza N, Grube E, Gerckens U, den Heijer P, Linke A, Luha O, et al. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) corevalve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. EuroIntervention. 2008 Aug;4(2):242-9. https://doi.org/10.4244/eijv4i2a43
17. Takagi H, Hari Y, Kawai N, Ando T; ALICE (All-Literature Investigation of Cardiovascular Evidence) Group. Meta-Analysis of Impact of Anemia and Hemoglobin Level on Survival After Transcatheter Aortic Valve Implantation. Am J Cardiol. 2019 Jan 15;123(2):306-14. https://doi.org/10.1016/j.amjcard.2018.09.042
18. Sannino A, Schiattarella GG, Toscano E, Gargiulo G, Giugliano G, Galderisi M, et al. Meta-Analysis of Effect of Body Mass Index on Outcomes After Transcatheter Aortic Valve Implantation. Am J Cardiol. 2017 Jan 15;119(2):308-16. https://doi.org/10.1016/j.amjcard.2016.09.031
19. Barbash IM, Barbanti M, Webb J, Molina-Martin De Nicolas J, Abramowitz Y, Latib A, et al. Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation. Eur Heart J. 2015 Dec 14;36(47):3370-9. https://doi.org/10.1093/eurheartj/ehv417
20. Oguri A, Yamamoto M, Mouillet G, Gilard M, Laskar M, Eltchaninoff H, et al. Impact of chronic kidney disease on the outcomes of transcatheter aortic valve implantation: results from the FRANCE 2 registry. EuroIntervention. 2015 Jan;10(9):e1-9. https://doi.org/10.4244/eijv10i9a183
21. Siddiqui WJ, Alvarez C, Aslam M, Bakar A, Khan MH, Aslam A, et al. Meta-Analysis Comparing Outcomes and Need for Renal Replacement Therapy of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement. Am J Cardiol. 2018 Aug 1;122(3):468-76. https://doi.org/10.1016/j.amjcard.2018.04.030
22. Tarantini G, Mojoli M, Urena M, Vahanian A. Atrial fibrillation in patients undergoing transcatheter aortic valve implantation: epidemiology, timing, predictors, and outcome. Eur Heart J. 2017 May 1;38(17):1285-93. https://doi.org/10.1093/eurheartj/ehw456
23. Tarantini G, Mojoli M, Windecker S, Wendler O, Lefèvre T, Saia F, et al. Prevalence and Impact of Atrial Fibrillation in Patients With Severe Aortic Stenosis Undergoing Transcatheter Aortic Valve Replacement: An Analysis From the SOURCE XT Prospective Multicenter Registry. JACC Cardiovasc Interv. 2016 May 9;9(9):937-46. https://doi.org/10.1016/j.jcin.2016.01.037
24. Onorati F, D'Errigo P, Barbanti M, Rosato S, Covello RD, Maraschini A, et al. Different impact of sex on baseline characteristics and major periprocedural outcomes of transcatheter and surgical aortic valve interventions: Results of the multicenter Italian OBSERVANT Registry. J Thorac Cardiovasc Surg. 2014 May;147(5):1529-39. https://doi.org/10.1016/j.jtcvs.2013.05.039